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August 25, 2003

CERTIFICATE OF MAILING 37 C.F.R 1.8

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August 25, 2003

Date

Robert E. Hanson

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SN 09/804.733; Entitled "RECOMBINANT PROTEINS CONTAINING

REPEATING UNITS" - Qi Wang, et al.

Our Ref. MONS:016US; Client Ref. 51718-US-01

Commissioner:

Please find enclosed:

- A Supplemental Response to Restriction Requirement; and 1.
- A return postcard to acknowledge receipt of these materials. Please date stamp and mail 2. this postcard.

Should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/MONS:016US.

Respectfully submitted,

Robert E. Hanson Reg. No. 42,628

REH/vv

Enclosures: As stated

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August 25, 2003 Date

Robert E. Hanson

SEP 01 2003

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Qi Wang et al.

Serial No.: 09/804,733

Filed: March 13, 2001

For: RECOMBINANT PROTEINS

CONTAINING REPEATING UNITS

Group Art Unit: 1638

Examiner: Kruse, David H.

Atty. Dkt. No.: MONS:016US

SUPPLEMENTAL RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Commissioner:

This paper is submitted in response to the Notice of Non-Responsive Amendment, for which the date for response is August 30, 2003, and in supplement to the Response to Restriction Requirement mailed in the case on May 5, 2003.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/MONS:016US.

In response to the restriction requirement which the Examiner imposed, Applicants elect, with traverse, to prosecute claims 1-18 and 20, *i.e.*, the Group V claims, and the sequence LKPNM with respect to the sequences referred to on page 14 of the restriction requirement.

With regard to claim Groups I-V, these are each drawn to a method for producing a recombinant protein containing two tandem repeat units in a host cell. The restricted claims all include the same claims, claims 1-19, save group V, which includes claims 1-18 and 20. The claims all have the same classification; class 435, subclass 69.1. The only cited difference among these groups are cell types, and this *limitation is not found in the independent claim*, claim 1. It thus may not reasonably be alleged that the claim groupings cannot be used together and have different modes of operation – they are from the same claims and have the same classification. No basis has been given to indicate that the cell type changes the mode of operation or ability to use the claims together. This is true with respect to Groups VII-XI, XV-XIX and XX-XXIV as well, which were also restricted based on cell types recited only in dependent claims.

Where the claims of an application define the same essential characteristics of a single disclosed embodiment, restriction therebetween should never be required. M.P.E.P. § 806.03. Applicants therefore respectfully request that the restrictions within the foregoing groups be withdrawn.

Applicants further note that, in addition to a showing that the claims are independent, a serious burden on the examiner must also be shown in order to properly maintain the restriction. M.P.E.P. § 803. No such showing has been provided or explained as is required pursuant to 35 U.S.C. §132. The fact that the recited claim groupings include the same claims and same classification of subject matter shows that such a burden is not present with regard to the recited groupings. For this and the foregoing reasons, Applicants respectfully request that the restriction within Groups I-V, VII-XI, XV-XIX and XX-XXIV be withdrawn.

With regard to the sequences identified on page 14 of the restriction requirement, no burden has been shown for examining the sequences together, as no search at all of the sequences is required. The novelty of the instantly claimed invention is independent of any given tandem repeat. In each of claims 9, 34, 57 and 62 Applicants are not claiming the sequences themselves. Still further, none of the sequences are longer than five amino acids, and more than half the listed sequences are three or fewer amino acids. There is therefore no undue burden in searching these sequences. Applicants thus respectfully request removal of the restriction between the sequences recited on page 14 of the restriction requirement.

Applicants finally note that Groups I-V, VII-XI, XV-XIX and XX-XXIV are linked by generic linking claims. In particular, each of Groups I-V and the sequences in claim 9 are linked by claim 1, Groups VII-XI and the sequences in claim 34 are linked by claim 27, Groups XV-XIX and the sequences in claim 73 are linked by claim 63 and Groups XX-XXIV and the sequences in claim 94 are linked by claim 85.

In a restriction requirement, generic or other linking claims should not be associated with any one of the linked inventions, and this fact should be clearly stated on the record. MPEP §814. This is because such claims must be examined with any one of the linked inventions that may be elected. In the instant case, the linking claims have not been segregated and it has not been stated on the record that such linking claims are present. Applicants therefore respectfully request such action.

With respect to the imposition of a restriction requirement as to cell types embraced by the generic linking claims, which *limitations are not found in the generic linking claim*, Applicants respectfully draw attention to the recent decision by the Court of Appeals for the Federal Circuit, which notes that an applicant may prosecute generic, linking claims "without

running afoul of the restriction requirement *because they are linking claims*." *In re Michael P. Doyle*, 293 F.3d 1355, 1360 (Fed. Cir., 2002), *citing* MPEP §809.03 (8th ed. 2001) (emphasis added). Indeed, the Court held that the failure to present generic claims in the original prosecution of an application was an error correctable by broadening reissue. *Id.* at 1361-1362. Further, the Federal Circuit noted that allowance of a linking claim prompts the examination of covered claims, stating that "The MPEP expressly provides that '[I]f a linking claim is allowed, the examiner <u>must</u> thereafter examine species if the linking claim is generic thereto, or he or she <u>must</u> examine the claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim." *Id.* at 1362., *citing* MPEP § 809.04 (emphasis added by the Court).

In the present case, the restrictions of Groups I-V, VII-XI, XV-XIX and XX-XXIV were imposed with respect to different cell types that are not listed in the generic linking claim, upon which each of the claims in the groupings depend and thus are linked. The claims linking each of these groups are also generic to the sequences recited in claims 9, 34, 73 and 94, respectively. To proceed with the restriction and not consider the generic linking claims would foreclose Applicants ability to have the generic linking claims properly examined. This is not permitted under the Federal Circuit's holding in *Doyle* and the procedures set forth in the MPEP.

In view of the foregoing, Applicants therefore additionally request that claim 1 be identified as linking currently named Groups I-V and the sequences in claim 9, that claim 27 be identified as linking Groups VII-XI and the sequences in claim 34, that claim 63 be identified as linking Groups XV-XIX and the sequences in claim 73 and that claim 85 be identified as linking Groups XX-XXIV and the sequences in claim 94.

The Examiner is invited to contact the undersigned attorney at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Attorney for Applicants

Robert E. Hanson Reg. No. 42,628

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Date: August 25, 2003